ATTACHMENT 5

USDA DOCUMENTS RE:

BSE COUNTRY

30 countries

(c) *Obtaining approval for exempt uses.* In order to receive exemptions for cherries or cherry products utilized for exempt purposes, handlers must apply to the Board for a new exemption or for renewal of an existing exemption by November 1 for the next succeeding year, except for the 1997 year only, handlers may apply through February 5, 1998. A handler shall have one crop year to dispose of cherries or cherry products to exempt outlets approved by the Board, unless granted a renewal. Handlers applying to the Board for a new exemption or for renewal of an existing exemption are subject to the following conditions:

(1) When applying to the Board for an exemption for new product development, handlers must detail the nature of their new product, how it differs from current, existing products and the anticipated short and long term sales volume for the exemption. It will be the Board staff's responsibility to analyze and investigate any request and upon completion of that analysis authorize or deny the exemption.

(2) When applying to the Board for an exemption for new market development, handlers must detail the nature of their new market, how it differs from current, existing markets and the anticipated short and long term sales volume for the exemption. It will be the Board staff's responsibility to analyze and investigate any request and upon completion of that analysis authorize or deny the exemption.

(3) When applying to the Board for an exemption for the development of export markets for tart cherries or cherry products (including juice and juice concentrate through June 30, 1998 only) in countries other than Canada, Mexico and Japan, including the expansion of sales in existing export markets, handlers must detail the nature of their product, specify whether such product differs from current products being sold in export markets, and estimate the anticipated short and long term sales volumes for the requested exemption.

(4) When applying to the Board for an exemption for experimental purposes, handlers must indicate the preliminary and/or developmental experimental activity. Such experimental purposes should be intended to result in new products, new applications and/or new markets for existing tart cherry products. Any exemption for experimental work shall be limited in scope, duration and volume which the proposing party shall specify at the time a request for exemption is made. In no case shall an exemption for experimental purposes last longer than five years or exceed 100,000 pounds raw product equivalent per handler of tart cherries during the duration of the experiment.

(d) *Review of applications.* A Board appointed subcommittee of three persons which shall include the manager (or a Board member acting in the Manager's stead), the public member and one industry person who is not on the Board, shall review applications for exemption or renewal of exemption and either approve or deny the exemption. Any denial of an application for exemption or renewal of an existing exemption shall be served on the applicant by certified mail and shall state the reasons for the denial. Within 10 days after the receipt of a denial, the applicant may file an appeal, in writing, with the Deputy Administrator, Fruit and Vegetable Programs, supported by any arguments and evidence the applicant may wish to offer as to why the application for exemption or renewal of exemption should have been approved. The Deputy Administrator upon consideration of such appeal will take such action as deemed appropriate with respect to the application for exemption or renewal of exemption.

(e) *Progress report.* Each handler that is granted an exemption must submit to the Board an annual progress report, due May 1 of each crop year. The progress report shall include the results of the exemption activity (comparison of intended activity with actual activity) for the year in its entirety, the volume of exempted fruit, an analysis of the success of the exemption program, and such other information as the Board may request.

(f) *Diversion credit; failure to meet terms and conditions of exemption.* Handler diversion certificates for exempt uses shall be issued to handlers provided that terms and conditions applicable to exempt uses are satisfied. Diversion certificates will not be issued to handlers for any volume of tart cherry products for which such terms and conditions are not satisfied and such cherries would be subject to all of the terms and conditions of §§ 930.41, 930.44, 930.51, 930.53, and §§ 930.55 through 930.57.

(g) *Failure to meet terms and conditions for exemption.* Upon termination of an exemption, any volume of tart cherry products that were granted an exemption but were not utilized for the authorized exempt purpose would be subject to all of the terms and conditions of §§ 930.41, 930.44, 930.51, 930.53, and §§ 930.55 through 930.57.

Dated: December 30, 1997.

Enrique E. Figueroa,

Acting Administrator, Agricultural Marketing Service.

[FR Doc. 98-283 Filed 1-5-98; 8:45 am]

BILLING CODE 3410-02-U

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Parts 94 and 96

[Docket No. 97-127-1]

Restrictions on the Importation of Ruminants, Meat and Meat Products From Ruminants, and Certain Other Ruminant Products

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Interim rule and request for comments.

SUMMARY: We are amending the regulations governing the importation into the United States of ruminants, meat and meat products from ruminants, and other ruminant products to restrict the importation of live ruminants, meat and meat products from ruminants, and certain other ruminant products from countries in which bovine spongiform encephalopathy (BSE) may exist. This action is necessary to ensure that animals and animal products affected with BSE are not imported into the United States.

DATES: Interim rule effective December 12, 1997. Consideration will be given only to comments received on or before March 9, 1998.

ADDRESSES: Please send an original and three copies of your comments to Docket No. 97-127-1, Regulatory Analysis and Development, PPD, APHIS, suite 3C03, 4700 River Road Unit 118, Riverdale, MD 20737-1238. Please state that your comments refer to Docket No. 97-127-1. Comments received may be inspected at USDA, room 1141, South Building, 14th Street and Independence Avenue SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays. Persons wishing to inspect comments are requested to call ahead on (202) 690-2817 to facilitate entry into the comment reading room.

FOR FURTHER INFORMATION CONTACT: Dr. Julia Sturm, Supervisory Staff Veterinarian, Products Program, National Center for Import and Export, VS, APHIS, USDA Center, Unit 40, 4700 River Road, Riverdale, MD 20737-1231, (301) 734-3399.

SUPPLEMENTARY INFORMATION:

Background

The regulations in 9 CFR parts 92, 93, 94, 95, and 96 (referred to below as the regulations) govern the importation of certain animals, birds, poultry, meat, other animal products and byproducts, hay, and straw into the United States in order to prevent the introduction of various animal diseases, including bovine spongiform encephalopathy (BSE).

BSE is a neurological disease of bovine animals and other ruminants and is not known to exist in the United States.

It appears that BSE is primarily spread through the use of ruminant feed containing protein and other products from ruminants infected with BSE. Therefore, BSE could become established in the United States if materials carrying the BSE agent, such as certain meat and other animal products and byproducts from ruminants infected with BSE, are imported into the United States and are fed to ruminants in the United States. BSE could also become established in the United States if ruminants from countries or other regions in which BSE exists are imported.

Sections 94.18, 95.4, and 96.2 of the regulations prohibit or restrict the importation of certain meat and other animal products and byproducts from ruminants that have been in regions in which BSE exists. These regions, which currently consist only of countries, are listed in § 94.18 of the regulations. Furthermore, § 93.404(a)(3) states that the Animal and Plant Health Inspection Service (APHIS) may deny the importation of ruminants from regions where a communicable disease such as BSE exists. The current regulations at § 94.18(a) list the following countries as regions in which BSE exists: Belgium, France, Great Britain, Northern Ireland, the Republic of Ireland, Luxembourg, The Netherlands, Oman, Portugal, and Switzerland.

We now consider it necessary to restrict the importation of ruminants, meat and meat products from ruminants, and certain ruminant products and byproducts not only from countries and other regions in which BSE is known to exist, but also from countries and other regions which, because of import requirements less restrictive than those that would be acceptable for import into the United States and/or because of inadequate surveillance, present a significant risk of introducing BSE. Specifically, we consider it necessary to apply these restrictions to all countries of Europe. In addition to the countries listed above, we are applying such restrictions to Albania, Austria, Bosnia-Herzegovina, Bulgaria, Croatia, the Czech Republic, Denmark, the Federal Republic of Yugoslavia, Finland, Germany, Greece, Hungary, Italy, the former Yugoslav Republic of Macedonia, Norway, Poland, Romania, the Slovak Republic, Slovenia, Spain, and Sweden.

Additionally, in this rule, in the list of regions in which BSE exists, we are including Great Britain and Northern Ireland under "United Kingdom," which also encompass The Falklands.

Reasons for New Restrictions

Our decision to establish the restrictions set forth in this interim rule is based on recent developments in Europe that lead us to believe that the BSE agent may be present, but as yet undetected, throughout Europe. The Netherlands, Belgium, and Luxembourg have recently reported their first cases of BSE in native-born cattle. Additionally, Belgium and Luxembourg have reported that cattle diagnosed with BSE were inadvertently processed into the animal food chain. Because of the movement of ruminants and ruminant products within Europe, the possibility exists that this potentially contaminated animal feed may have been moved from Belgium and Luxembourg to other European countries.

We consider the risk posed by this potential movement to be especially great in light of new scientific research that has identified BSE infectivity in bone marrow, dorsal root ganglion, and trigeminal ganglion. This new research expands the list of specific bovine tissues and organs of concern for BSE infectivity. Previously, the list included only terminal (distal) ileum, brain, eye (retina), and spinal cord. Based on ongoing research, it appears likely that other tissues may contain the BSE infectious agent.

Therefore, we are amending the list in § 94.18(a) to include the countries discussed above. Due to the research findings that additional tissues may contain the BSE infectious agent, we are also amending § 94.18(b) to remove an exception that allowed fresh, frozen, and chilled meat and meat products to be imported into the United States from countries listed in § 94.18(a) if the meat was deboned, free of visually identifiable lymphatic and nerve tissue, and met certain other requirements.

In part 96 of the regulations, § 96.2(b) prohibits the importation of bovine casing, except stomachs, that originated in or were processed in any country where BSE exists, as listed in existing § 94.18(a). In this interim rule, we are rewording that reference in § 96.2(b) so that it also encompasses the countries we are adding to § 94.18(a) in this interim rule, and are changing the heading to the section accordingly. Additionally, we are expanding the prohibition on casings to include those from both bovines and other ruminants.

Because the following products present a minimal risk of BSE transmission, we have not been prohibiting their importation from BSE-affected countries under the existing regulations, and we are excluding them from the restrictions established by this interim rule: semen, milk and milk products, hides and skins, tallow and tallow derivatives, and certain blood products used in microbiologic media.

Procedures for Requesting Removal of Restrictions

In § 94.18(a)(3) of this rule, we provide that countries or other regions that wish to request removal from the list of regions considered high risk for BSE must submit to APHIS certain information described in § 92.2 of the regulations. This information is as follows:

1. The authority, organization, and infrastructure of the veterinary services organization in the region (country).
2. Disease status—i.e., is the BSE agent known to exist in the region? If "yes," at what prevalence? If "no," "when was the most recent diagnosis?
3. The status of adjacent regions with respect to the agent.
4. The extent of an active disease control program, if any, if the agent is known to exist in the region.
5. The degree to which the region is separated from regions of higher risk through physical or other barriers.
6. The extent to which movement of animals and animal products is controlled from regions of higher risk, and the level of biosecurity regarding such movements.
7. Livestock demographics and marketing practices in the region.
8. The type and extent of disease surveillance in the region—e.g., is it passive and/or active; what is the quantity and quality of sampling and testing?
9. Diagnostic laboratory capabilities.
10. Policies and infrastructure for animal disease control in the region—i.e., emergency response capacity.

Emergency Action

The Administrator of the Animal and Plant Health Inspection Service has determined that an emergency exists that warrants publication of this interim rule without prior opportunity for public comment. We are making this

action effective retroactively to December 12, 1997, which is the date APHIS issued a policy stating it had stopped issuing import permits for the live ruminants and ruminant products and byproducts covered by this interim rule. This effective date is necessary to ensure that ruminant and ruminant products and byproducts infected with BSE are not imported into the United States.

Because prior notice and other public procedures with respect to this action are impracticable and contrary to the public interest under these conditions, we find good cause under 5 U.S.C. 553 to make the rule effective December 12, 1997. We will consider comments that are received within 60 days of publication of this rule in the **Federal Register**. After the comment period closes, we will publish another document in the **Federal Register**. It will include a discussion of any comments we receive and any amendments we are making to the rule as a result of the comments.

Executive Order 12866 and Regulatory Flexibility Act

This rule has been reviewed under Executive Order 12866. For this action, the Office of Management and Budget has waived its review process required by Executive Order 12866.

This emergency situation makes compliance with section 603 and timely compliance with section 604 of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) impracticable. If we determine this rule would have a significant economic impact on a substantial number of small entities, then we will discuss the issues raised by section 604 of the Regulatory Flexibility Act in our Final Regulatory Flexibility Analysis.

Executive Order 12988

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Preempts all State and local laws and regulations that are inconsistent with this rule; (2) has retroactive effect to December 12, 1997; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection or recordkeeping requirements included in this rule have been approved by the Office of Management and Budget (OMB), and there are no new requirements. The assigned OMB control number is 0579–0040.

List of Subjects

9 CFR Part 94

Animal diseases, Imports, Livestock, Meat and meat products, Milk, Poultry and poultry products, Reporting and recordkeeping requirements.

9 CFR Part 96

Imports, Livestock, Reporting and recordkeeping requirements.

Accordingly, we are amending 9 CFR, chapter I, subchapter D, as follows:

PART 94—RINDERPEST, FOOT-AND-MOUTH DISEASE, FOWL PEST (FOWL PLAGUE), EXOTIC NEWCASTLE DISEASE, AFRICAN SWINE FEVER, HOG CHOLERA, AND BOVINE SPONGIFORM ENCEPHALOPATHY; PROHIBITED AND RESTRICTED IMPORTATIONS

1. The authority citation for part 94 continues to read as follows:

Authority: 7 U.S.C. 147a, 150ee, 161, 162, and 450; 19 U.S.C. 1306, 21 U.S.C. 111, 114a, 134a, 134b, 134c, 134f, 136, and 136a; 31 U.S.C. 9701; 42 U.S.C. 4331 and 4332; 7 CFR 2.22, 2.80, and 371.2(d).

§ 94.18 [Amended]

2. Section 94.18 is amended by revising the heading to the section and paragraphs (a) and (b) to read as follows:

§ 94.18 Restrictions on importation of meat and edible products from ruminants due to bovine spongiform encephalopathy.

(a)(1) Bovine spongiform encephalopathy exists in the following regions: Belgium, France, the Republic of Ireland, Luxembourg, Oman, The Netherlands, Portugal, Switzerland, and the United Kingdom.

(2) The following regions, because of import requirements less restrictive than those that would be acceptable for import into the United States and/or because of inadequate surveillance, present and undue risk of introducing bovine spongiform encephalopathy into the United States: Albania, Austria, Bosnia-Herzegovina, Bulgaria, Croatia, the Czech Republic, Denmark, the Federal Republic of Yugoslavia, Finland, Germany, Greece, Hungary, Italy, the Former Yugoslav Republic of Macedonia, Norway, Poland, Romania, the Slovak Republic, Slovenia, Spain, and Sweden.

(3) A region may request at any time that the Administrator considers its removal from a list set forth in paragraphs (a)(1) or (a)(2) of this section by following the procedures set forth in §§ 92.2(b) (1) through (4), 92.2(b) (5) through (11), and 92.2(c) of this chapter.

(b) Except as provided in paragraph (d) of this section, the importation of fresh, frozen, and chilled meat, meat products, and edible products other than meat (excluding gelatin, milk, and milk products), from ruminant that have been in any of the countries listed in paragraph (a) of this section is prohibited.

* * * * *

PART 96—RESTRICTION OF IMPORTATIONS OF FOREIGN ANIMAL CASINGS OFFERED FOR ENTRY INTO THE UNITED STATES

3. The authority citation for part 96 continues to read as follows:

Authority: 21 U.S.C. 111, 136, 136a; 7 CFR 2.22, 2.80, and 371.2(d).

§ 96.2 [Amended]

4. Section 96.2 is amended by revising the heading to the section and paragraph (b) to read as follows:

§ 96.2 Prohibition of casings due to African swine fever and bovine spongiform encephalopathy.

* * * * *

(b) The importation of casings, except stomachs, from bovines and other ruminants that orginated in or were processed in any region listed in § 94.18(a) of this subchapter is prohibited.

Done in Washington, DC, this 31st day of December 1997.

Joan M. Arnoldi,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 98–286 Filed 1–5–98; 8:45 am]

BILLING CODE 3410–34–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 520, and 558

New Animal Drugs and Related Products; Change of Sponsor; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a document that appeared in the **Federal Register** of October 23, 1997 (62 FR 55159). The document amended the animal drug regulations to reflect a change of sponsor for three new animal drug applications (NADA's) and three abbreviated new animal drug applications (ANADA's) from Wade-Jones Co., Inc., and its manufacturing subsidiary Arkansas Micro Specialties,

The following criteria are specific for BSE risk factors. In addition to these, the standard evaluation of veterinary infrastructure must also be met.

The OIE standards are in italics in this document, with our relevant criteria in bold listed immediately after each standard.

Article 3.2.13.1:

The BSE status of a country can only be determined by continuous surveillance and monitoring. The minimum requirements for effective surveillance are:

1) compulsory notification and clinical investigation of suspect cases:

BSE must be a notifiable disease supported by the appropriate statutory authority. Information should be provided on an ongoing basis to practitioners and farmers to educate them about the disease and notification requirements.

Reported suspect cases must be examined as part of an official investigation. As a minimum, clinical suspect case must include animals showing either chronic debilitating disease or progressive neurologic CNS signs unresponsive to treatment in cattle over 30 months of age. Appropriate samples should be collected and submitted for diagnosis. There are control measures on the carcass or animal until a determination has been made on suspect cases.

2) a risk assessment identifying the potential hazards for BSE occurrence:
a) risk arising by:
i) importation of animals or embryos/ova which are potentially infected with a transmissible spongiform encephalopathy (TSE):

Embryos/ova: Must have import requirements to minimize the risk of TSE transmission from imported embryos/ova.

Live ruminants: Must not have imported ruminants from the UK since1990. Ruminants imported from any country where BSE has been identified in native animals have been traced and are routinely monitored. Regulations should restrict the importation of ruminants from other countries where BSE has been identified in native cattle or which have high risk factors for BSE occurrence.

ii) importation and feeding of potentially contaminated animal feedstuff to cattle:

Have not imported rendered ruminant protein, or animal feed containing rendered ruminant protein, or ruminant offal intended for incorporation into animal feed from the UK since 1987. No importations of such products from other countries where BSE has been identified in native cattle or which have high risk factors for BSE occurrence shall take place.

b) indigenous risks:

i) consumption, by cattle, of contaminated, animal-derived proteins arising from transmissible spongiform encephalopathy-infected animals and rendering processes which do not inactivate the agent:

A ruminant-to-ruminant feed ban is in place and effectively enforced.

Must have ongoing active surveillance for other known animal TSE's.

ii) potential vertical transmission of BSE from cows originated from infected countries;

Ruminants imported from any country where BSE has been identified in native animals have been traced and are routinely monitored. Offspring of BSE affected cows are traced and restricted.

3) a continuous BSE surveillance and monitoring system with emphasis on risks identified in point 2) above; and

Must have had an ongoing surveillance program in place for the past 5 years.

4) examination in an approved laboratory of brain material from cattle older than 20 months displaying signs of progressive neurologic disease in accordance with the diagnostic techniques set out in the Manual. A sufficient number of investigations as indicated in Table I of the Guidelines for Continuous Surveillance and Monitoring of BSE (Appendix VIIIb of document 65 SG/12/CS1) should be carried out annually;

In countries where progressive neurologic disease incidence is low, surveillance should be targeted at cattle older than four years of age displaying other progressive disease conditions;

Must meet this requirement as stated and provide documentation of laboratory procedures. In cases of progressive debilitating or neurologic disease where a diagnosis cannot be made, a recognized alternative additional diagnostic method should be done in addition to histology.

5) records of the number and results of investigations should be maintained for at least 7 years.

Must meet this requirement as stated.

Article 3.2.13.2:

Countries may be considered free of BSE if:
1) they have implemented a risk management strategy to address any risk as identified in Article 3.2.13.1. point 2); and

The country must have an appropriate risk management strategy including

evidence of its effective implementation that addresses risks through importation of live ruminants, embryos/ova, ruminant feed material or other identified indigenous risks.

2) the feeding of meat-and-bone meal to cattle derived from ruminants originating from animal TSE infected countries, or countries which do not have an effective and continuous surveillance and monitoring system as described in Article 3.2.13.1. points 3) and 4) has been banned and is effectively enforced;

Stated previously

AND

3) a) there has been no clinical case of BSE, the disease is notifiable, and an effective and continuous surveillance and monitoring system is practised, as described in Article 3.2.13.1. points 3) and 4); or

Stated previously

b) all cases of BSE have been clearly demonstrated to originate directly from the importation of live cattle originating from BSE infected countries, provided that the disease is made notifiable and suspect animals are slaughtered, investigated and, if disease is confirmed, completely destroyed and an effective and continuous surveillance and monitoring system is practised, as described in Article 3.2.13.1. points 3) and 4); or

Must meet this requirement.

c) BSE has been eradicated (under study).

BSE SURVEILLANCE AND MONITORING QUESTIONNAIRE

The OIE standards (International Animal Health Code, Chapter 3.2.13) are in italics in this document, with the relevant questions listed immediately after the standard.

Article 3.2.13.1:

The BSE status of a country can only be determined by continuous surveillance and monitoring. The minimum requirements for effective surveillance are:

1) compulsory notification and clinical investigation of suspect cases:

Is BSE a notifiable disease? If so, by whom - private veterinarian, farmer, etc...? Please cite the legal authority. Please describe educational efforts about BSE and to whom they are given.

Describe the process for an investigation of suspects, including a description of your clinical definition of suspect, including age. Who performs the investigation? What controls are placed on the animal/carcass, herd, offspring, etc..?

2) a risk assessment identifying the potential hazards for BSE occurrence:
a) risk arising by:
i) importation of animals or embryos/ova which are potentially infected with a transmissible spongiform encephalopathy (TSE):

Please list the countries which you consider affected with BSE. Do you restrict the import of ruminants and/or their embryos from BSE-affected countries?

Have live ruminants been imported? If yes, list totals imported by country of origin and date of importation, from 1988 until present. What requirements, if any, related to TSE's were necessary for these imports?

Have bovine or ovine embryos been imported? If yes, list totals imported by country of origin and date of importation, from 1988 until present. What requirements, if any, related to TSE's were necessary for these imports?

ii) importation and feeding of potentially contaminated animal feedstuff to cattle:

Has rendered animal protein, or animal feed containing rendered animal protein, been imported? If yes, list totals imported by country of origin and date of importation - (if possible to separate by mammalian protein vs. non-mammalian please do so) - from 1987 until present. What requirements, if any, were necessary for these importations? Are any post-import requirements in place for these products? Please describe these post-import requirements in detail.

Has any ruminant offal been imported? If yes, list totals of each product imported by country of origin and date of importation, from 1987 until present. What restrictions are in place for either the import of these products or their end use after import?

b) Indigenous risks:

i) consumption, by cattle, of contaminated, animal-derived proteins arising from transmissible spongiform encephalopathy-infected animals and rendering processes which do not inactivate the agent:

Do you restrict feeding ruminant (or mammalian) products to ruminants? If yes, describe specifically the restrictions and the month and year they took effect. How are these restrictions enforced? Do you use testing procedures to determine the freedom of mammalian protein? If yes, please describe the procedures and the results.

Do you restrict tissues which may be rendered to produce meat-and-bone meal? If yes, describe the restrictions and when they took effect. Do you require specific time and temperature requirements for rendering processes? If yes, describe these requirements and when they took effect.

Is scrapie a notifiable disease in your country? Please list how many annual cases of scrapie you have had and the toal adult sheep population, from 1990 until present. What measures are taken when a positive scrapie animal is identified? What other control measures, if any, apply to scrapie? Have you had any cases of transmissible spongiform encephalopathies in other species (except human) since 1990? If yes, please describe. What type of surveillance is done for TSE's other than scrapie and BSE?

ii) potential vertical transmission of BSE from cows originated from infected countries;

Have you imported cattle from BSE affected countries? If yes, please specify totals from each country and purpose (i.e., breeding, feeding, immediate slaughter) by year. Have these animals been located? Are they routinely monitored or controlled in any way? Are their brains examined for BSE when they die? Have you imported sheep from BSE affected countries? If yes, please specify totals from each country and purpose, by year. Have any cases of scrapie been confirmed in sheep imported from BSE affected countries?

3) a continuous BSE surveillance and monitoring system with emphasis on risks identified in point 2) above; and

Describe in general your surveillance system. How are animals selected to be tested for BSE - please describe any clinical case definitions, including age? What is the population from which you are testing for BSE?

4) examination in an approved laboratory of brain material from cattle older than 20 months displaying signs of progressive neurologic disease in accordance with the diagnostic techniques set out in the Manual. A sufficient number of investigations as indicated in Table I of the Guidelines for Continuous Surveillance and Monitoring of BSE (Appendix VIIIb of document 65 SG/12/CS1) should be carried out annually:

in countries where progressive neurologic disease incidence is low, surveillance should be targeted

at cattle older than four years of age displaying other progressive disease conditions;

How many samples have been examined for BSE? Please list totals from the years 1990 until present in the following format:

Year	Total - cattle > 20 months of age with progressive CNS signs	Total - cattle > 20 months of age with progressive debilitating signs	Other - please explain

How many cases of BSE, if any, have been diagnosed? How many samples have been examined for other TSE's? Please provide this information with totals by species and year.

Please specify the total population of adult cattle (dairy and beef), and adult sheep and goats. If known, please specify population of wild and captive cervids, zoo ruminants, and exotic felines.

What laboratories are performing these tests? Please include a copy of the laboratory standard operating procedures (SOP's) for tests used. If an SOP is not available, please include minimal information on areas of the brain examined histologically and supplemental tests used, i.e., immunohistochemistry, Western blot, SAF. Please specify when supplemental tests are used and the number completed each year. Describe the training and experience of laboratory personnel with BSE.

5) records of the number and results of investigations should be maintained for at least 7 years.

What records are maintained relevant to BSE surveillance? How long are these maintained?

Article 3.2.13.2:

Countries may be considered free of BSE if:
1) they have implemented a risk management strategy to address any risk, as identified in Article 3.2.13.1. point 2); and

If additional risk management procedures not previously listed have been implemented, please describe.

2) the feeding of meat-and-bone meal to cattle derived from ruminants originating from animal TSE infected countries, or countries which do not have an effective and continuous surveillance and monitoring system as described in Article 3.2.13.1. points 3) and 4) has been banned and is effectively enforced;

If you have additional information not provided previously in reference to feed ban, please list here. There is no need to repeat previously stated material.

AND

3) a) there has been no clinical case of BSE, the disease is notifiable, and an effective and continuous surveillance and monitoring system is practised, as described in Article 3.2.13.1. points 3) and 4); or

If you have additional information not provided previously in reference to monitoring and surveillance, please list here. There is no need to repeat previously stated material.

b) all cases of BSE have been clearly demonstrated to originate directly from the importation of live cattle originating from BSE infected countries, provided that the disease is made notifiable and suspect animals are slaughtered, investigated and, if disease is confirmed, completely destroyed and an effective and continuous surveillance and monitoring system is practised, as described in Article 3.2.13.1. points 3) and 4); or

If BSE has been diagnosed in your country: Describe each case of BSE diagnosed in the past 7 years, including relevant epidemiology.

c) BSE has been eradicated (under study).